UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: January 12, 2021

SUBJECT: **Aldicarb**: Characterization of Citrus Uses on Dietary Exposures Estimates for *N*-Methyl Carbamate Cumulative Risk Assessment

PC Code: 098301
Decision No.: 549655
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D460600
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: 116-06-3
40 CFR: NA

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The Registration Division (RD) requested the Health Effects Division (HED) to characterize the impact on cumulative dietary exposure estimates for *N*-methyl carbamate class of pesticides. Exposure to aldicarb based on the previously active registration on citrus was included in the finalized 2007 report *Revised N-Methyl Carbamate Cumulative Risk Assessment* (NMC CRA). There are multiple lines of evidence suggesting that the proposed aldicarb use on citrus would not significantly impact the cumulative dietary exposure (i.e., exposure through food and water) estimates for the class of NMC pesticides. For food, exposure estimates from the NMC CRA and an analysis of more recent residue data from USDA Pesticide Data Program (PDP) provide quantitative support for concluding that the proposed use for aldicarb on citrus would not significantly impact the cumulative dietary exposure estimates. For water, estimated drinking water concentrations (EDWCs) from the NMC CRA and the similarity of the proposed aldicarb-citrus use (e.g., application rate and

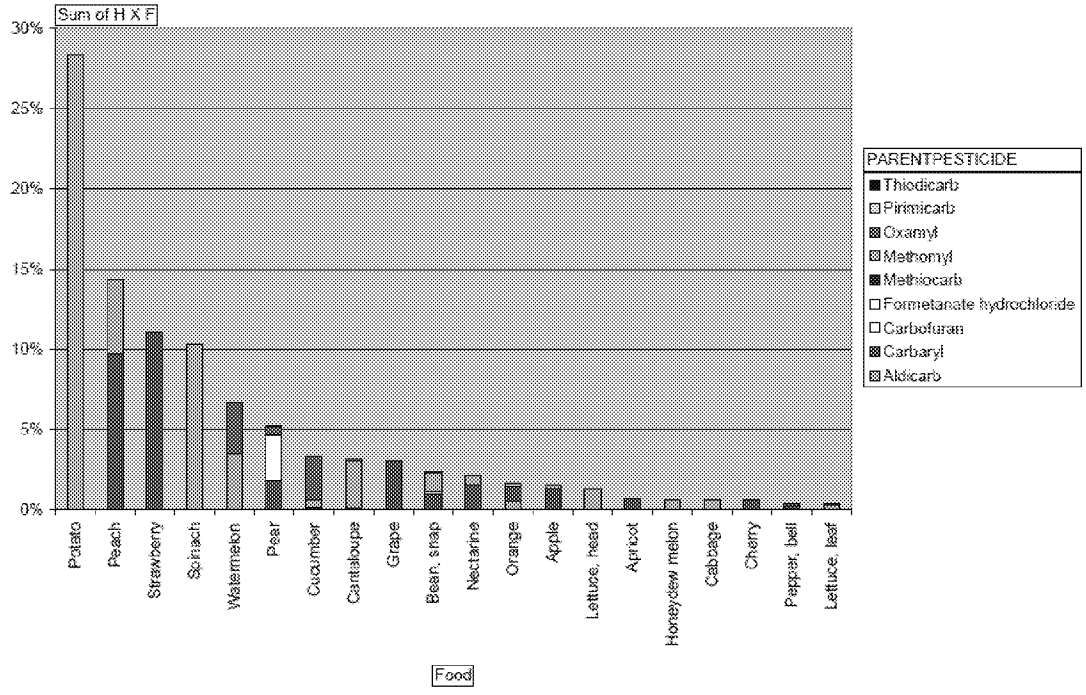
well-set back distance) to that modeled in the NMC CRA provide quantitative support for concluding the proposed use would not significantly impact cumulative dietary exposure estimates.

Food Exposure Characterization

For the 2007 NMC CRA, **food exposure** to aldicarb was estimated based on measured pesticide residues in orange, orange juice, and grapefruit[1]. For the most sensitive subpopulation, children 1-2 years old, the food exposure to aldicarb for these citrus foods was minimal for those at high-end of the exposure distribution (see **Figure I.C-1** excerpted from the [HYPERLINK "https://beta.regulations.gov/document/EPA-HQ-OPP-2008-0347-0029"]). Additionally, when conducting cumulative risk assessments, HED avoids exposure assumption that compound conservatisms. For example, non-detectable residues in food are assumed to be zero rather than assigning a default value (e.g., ½ LOD) to food samples that may have been treated, but have residues below the limit of detection (LOD). Single-chemical assessments may use percent crop treated (PCT) information to determine the fraction of food samples that are treated, but have undetectable residues. Since PCT information is not used for cumulative risk assessments to adjust residue, updates to PCT estimates for the aldicarb citrus uses would not affect food exposure estimates for the NMC CRA.

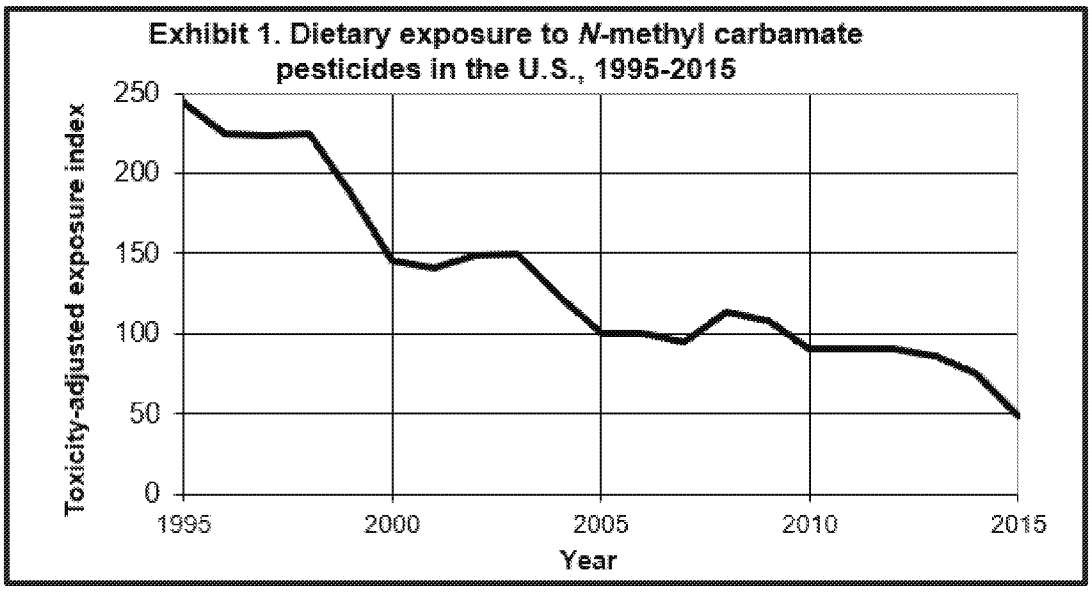
[1] USDA Pesticide Data Program (PDP) collects thousands of food samples annually and analyzes these samples for residues of hundreds of pesticides. Residue data from PDP was used to estimate food exposure for the NMC CRA. PDP found a number of detectable residues of aldicarb or its metabolites in grapefruit, orange, and orange juice. More specifically, the number of detectable residues (and years sampled) were 4 out of 1462 grapefruit samples with concentrations <= 0.063 ppm (2005-2006); 13 out of 4864 orange sample with concentration <= 0.025 ppm (1994-1996, 2000-2001, & 2004-2005); and 46 out of 2879 orange juice samples with concentrations <= 0.035 ppm (1997-1998 & 2004-2006).

Figure I.C-1. Relative Contribution of Crop/Chemical Pairs to Top 0.2 Percentile of Cumulative Distribution for Children 1-2



Additionally, the Health Effects Division has been working on toxicity-adjusted dietary index for the NMC pesticides, which tracks changes in exposure estimates over time based on measured pesticide residue data collected annually by USDA PDP. The dietary exposure index was adjusted for the differences in toxicity between the NMC pesticides using the same relative potency factors (RPF)[2] documented in the [HYPERLINK "https://beta.regulations.gov/document/EPA-HQ-OPP-2008-0347-0029"]. This draft toxicity-adjusted dietary indicator indexes NMC food exposures to 100 for the baseline year 2006. As shown in **Exhibit 1**, the dietary index indicates exposure to NMCs through food decreased ~50% from 2006 to 2015 based on reduction in residues observed in USDA PDP data. In more recent years, PDP residues on orange (2009-2010 & 2015), orange juice (2011-2012) and grapefruit (2015) have minimal impact on the 99.9th percentile of exposure for children 1-2 years old. To determine the potential impact of the proposed aldicarb citrus use on cumulative food exposure, HED included the years of PDP residues data with the highest residues in the dietary index: orange (2005), orange juice (2005), and grapefruit (2006). Including aldicarb citrus residue from PDP with the highest observed residues did not significantly impact exposure (~0.1%) at the 99.9th percentile of exposure for children 1-2 years old.

[2] A comparison of the endpoints and uncertainty & safety factors between the 2016 single-chemical assessment and the 2007 NMC CRA indicates aldicarb would be considered 3.6 times more toxic in the single-chemical assessment: BMD_{10}(mg/kg/day): 0.06 (CRA) vs 0.03 (single-chemical assessment); FQPA SF: 2 (CRA) vs 4.8 (single-chemical assessment); and interspecies UF: 2 (CRA) vs 1 (single-chemical assessment).



Drinking Water Exposure Characterization

For the NMC CRA, **drinking water exposure** to aldicarb from citrus uses was estimated using modeling approaches and assumptions, including application rates, similar to those for the proposed aldicarb-citrus use. In the NMC CRA, application rates for aldicarb on citrus ranged from 3.85 lb ai/A with 2 applications in FL to 4.69 lb ai/A with 1 application in TX. These are similar to the proposed use of 1 application at 4.95 lb a.i./A. Additionally, both the cumulative and the new single-chemical aldicarb DWA assumed aldicarb was available for runoff into surface water for in-furrow (incorporated) applications. Furthermore, consideration of percent crop treated for surface water sources of drinking water and a distribution of EDWC concentrations were provided to HED to refine the aPAD for both the NMC CRA and the new single-chemical aldicarb DWA for the proposed use.

The NMC CRA considered both surface and groundwater-sources of drinking water, focusing on areas of high potential exposures (based on total pounds applied for all NMC uses, vulnerability of the drinking water sources, and the relative toxicities of the individual NMCs). Aldicarb was a major driver for drinking water in the NMC, particularly for private groundwater sources. When the NMCs were assessed in 2007, the existing labels for aldicarb specified a 1000-foot setback for wells for citrus use in sandy soils. As a result, estimated drinking water exposures were below human health dietary concerns. The proposed new use label includes the 1000 ft well set-back for vulnerable soils in FL, so that exposures in groundwater sources of drinking water are not expected to differ from what was estimated in the NMC CRA.

For surface water sources of drinking water, EDWCs from aldicarb use on peanuts and cotton drove dietary exposure through water in the NMC CRA; the human health dietary margins of exposure (MOEs) were all well above 10 indicating no risk concerns. EDWCs from aldicarb use on citrus were at least an order of magnitude less than those from peanut and cotton use, in part due to a lower percent crop treated on citrus and to differences in runoff vulnerabilities in citrus vs cotton/peanut growing areas. Because citrus is grown in

different areas than peanuts and cotton, an increase in surface water EDWCs for aldicarb in the citrus-growing areas of FL and TX would not increase the overall NMC exposure due to surface water consumption, which is driven by peanut and cotton use that occur in a different region.

Furthermore, the current proposed action restricts application of aldicarb to 100,000 acres/year, at a proposed maximum use rate of 4.95 lb a.i./A. However, it is noted that the historical average rate for aldicarb has been lower than this rate, and growers might attempt to maximize the number of acres treated with a limited supply but still need to apply an at efficacious rate. While the application rate is anticipated to vary over the 100,000 treated acres, a rate lower than the proposed maximum may be used to allow for maximum treatment of the restricted number of acres. Therefore, the EDWCs may overestimate levels in areas that use a lower rate.